Individual Safety Report

3318158-4-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CDER

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Form Approved: OMB No. 0910-0291 Expires: 12/
See OMB statement on re

FDA Use Only

Triage unit sequence # 107266

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 67 yo or Date of birth:

3. Sex: ☑ female ☐ male

4. Weight: 61 lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☑ other: complicated stay

3. Date of event (mo/day/yr): 4/20/99

4. Date of this report (mo/day/yr): 7/27/99

5. Describe event or problem

patient in house for brachial plexopathy. severe pain. Neutopits discovered that at home she'd been taking 10-15 percocet per day as well as 4-6 vicodin. (6.8 g tylenol) → LFT's elevated

6. Relevant tests/laboratory data, including dates

alk phos 378 (H) hep B & C (-)
AST 76 (H)
ALT 149 (H)
gamma gt 1119 (H)
amylase 102 (H)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

morphine allergy

CTU 107266

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 percocet
#2

2. Dose, frequency & route used
#1 10-15 po per day
#2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 chronic
#2

4. Diagnosis for use (indication)
#1 pain
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☑ no ☐ does not apply
#2 ☐ yes ☐ no ☐ does not apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ does not apply
#2 ☐ yes ☐ no ☐ does not apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

Vicodin, ambien, valium } chronic

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
model #
catalog #
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted] RPh Healthcare

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.